

CLAIMS:

1. An instrumented paper diary for recording data, comprising:
 - at least one paper form for recording data; and
 - 5 electronic instrumentation for generating an electronic record containing information regarding use of the diary.
- 10 2. The instrumented paper diary of claim 1, further comprising an interface for transferring the electronic record to a computer.
- 15 3. The instrumented paper diary of claim 1, wherein the electronic instrumentation includes a sensor for detecting when a subject uses the paper diary.
4. The instrumented paper diary of claim 3, wherein the sensor comprises an optical sensor for detecting when the paper diary is opened.
- 15 5. The instrumented paper diary of claim 4, wherein the sensor comprises a sensor to detect changes in light levels.
- 20 6. The instrumented paper diary of claim 3, wherein the sensor comprises a mechanical sensor for detecting when a user opens the diary.
7. The instrumented paper diary of claim 3, wherein the sensor detects when the diary is closed.
- 25 8. The instrumented paper diary of claim 3, wherein the electronic record captures and stores a time corresponding to when the sensor detects that the subject uses the paper diary.
- 30 9. The instrumented paper diary of claim 3, wherein the sensor is located underneath a writing surface of the paper form to detect when a user writes in the diary.

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10. The instrumented paper diary of claim 3, wherein the sensor detects movement of the diary.

11. The instrumented paper diary of claim 3, further comprising a tamper sensor for
5 detecting when a subject tampers with the electronic instrumentation.

12. The instrumented paper diary of claim 1, further comprising a pen connected to the diary to allow a user to record data and a time on the paper form.

10 13. The instrumented paper diary of claim 12, wherein the pen includes a sensor to detect when the user writes in the diary.

14. The instrumented paper diary of claim 1, wherein the electronic instrumentation includes a database to store the electronic record as a computer file.

15 15. The instrumented paper diary of claim 1, wherein the electronic record captures and stores an event indicative of use of the diary, together with a time at which the event occurs.

20 16. The instrumented paper diary of claim 15, wherein the electronic record further stores the date at which the event occurs.

17. The instrumented paper diary of claim 15, wherein said event comprises opening the diary.

25 18. The instrumented paper diary of claim 15, wherein said event comprises closing the diary.

19. The instrumented paper diary of claim 1, wherein the electronic instrumentation is
30 visible to a user of the paper diary.

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20. The instrumented paper diary of claim 19, further comprising a graphical display for displaying the electronic record to the user of the diary.

21. The instrumented paper diary of claim 1, wherein the electronic instrumentation is covertly connected to the paper form, such that the electronic instrumentation is hidden from a user of the diary.

22. A subject compliance monitoring system, comprising:
an instrumented paper diary including paper forms allowing a subject to enter
10 data and electronic instrumentation for generating an electronic record of diary use; and
an electronic device for displaying and viewing the electronic record.

23. The subject compliance monitoring system of claim 22, further comprising a reader for transferring the electronic record from the instrumented paper diary to the electronic
15 device.

24. The subject compliance monitoring system of claim 23, wherein the reader includes a cable connectable to an interface port on the electronic device.

20 25. The subject compliance monitoring system of claim 22, wherein the electronic device comprises a personal computer.

26. A device for monitoring subject compliance in a clinical trial, comprising:
an electronic device for use with a paper diary, wherein the electronic device
25 generates an electronic record tracking clinical trial data.

27. The device of claim 26, further comprising a paper diary in communication with the electronic device for manually recording clinical trial data.

30 28. The device of claim 27, wherein the electronic device comprises a sensor for detecting when a user records said clinical trial data.

29. The device of claim 28, wherein the electronic record logs a time when the user records said clinical trial data.

30. The device of claim 28, wherein the electronic record logs a date when the user 5 records said clinical trial data.

31. The device of claim 28, wherein the electronic record logs the duration of a time period during which the user records said clinical trial data.

10 32. The device of claim 28, wherein the electronic record is compared to the clinical trial data in the paper diary to verify the clinical trial data in the paper diary.

33. A method of monitoring subject compliance, comprising:
15 detecting an event related to data entry in a paper diary for recording data; and
capturing and storing a characteristic of the event to generate an electronic record of said data entry.

34. The method of claim 33, wherein said step of detecting an event comprises
detecting when the paper diary is opened.
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35. The method of claim 33, wherein said step of detecting an event comprises
detecting when the paper diary is closed.

36. The method of claim 33, wherein said step of detecting an event comprises
25 detecting when a subject opens the paper diary.

37. The method of claim 33, wherein the step of detecting an event comprises detecting
when a subject closes the paper diary.

30 38. The method of claim 33, wherein said characteristic comprises a time of the event.

39. The method of claim 33, wherein said characteristic comprises a date of the event.

40. The method of claim 33, wherein said event comprises use of the paper diary to record data.

5 41. The method of claim 40, wherein said electronic record stores the time and date of the use of the diary.

42. A method of confirming data obtained in a clinical trial, comprising:
generating an electronic record containing information regarding use of a paper
10 diary for recording clinical trial data; and
comparing said electronic record with written clinical trial data in the paper
diary.

43. The method of claim 42, wherein the electronic record records a time when a
15 subject uses the diary.

44. The method of claim 43, wherein the subject writes a time corresponding to diary use in the diary.

20 45. The method of claim 44, wherein said written clinical trial data is considered valid if the time written by the subject corresponds to the time in the electronic record when the subject uses the diary.

46. The method of claim 44, wherein said written clinical trial data is considered
25 falsified if the time written by the subject does not correspond to the time in the electronic record when the subject uses the diary.

47. A method of monitoring subject compliance in a clinical trial, comprising:
providing a subject with an instrumented paper diary for recording clinical trial
30 data; and
tracking the subject's use of the instrumented paper diary.

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48. The method of claim 47, wherein the step of tracking the subject's use comprises generating an electronic record of when the subject uses the instrumented paper diary.

49. The method of claim 48, wherein the subject writes the clinical trial data and a time 5 corresponding to the clinical trial data in the instrumented paper diary.

50. The method of claim 49, further comprising the step of comparing the time corresponding to the clinical trial data written by the user with information in said electronic record to confirm whether a time written in the diary corresponds to use of the 10 diary.

51. A method of making an instrumented paper diary, comprising:
providing a paper diary including paper forms for a user to record data;
providing electronic instrumentation for tracking use of the diary; and
15 connecting said electronic instrumentation to the paper diary to record when the diary is in use.